REMARKS

Claims 1-27 are pending. Claims 1-27 are rejected.

Summary of the Invention of the Present Application:

The invention of the present application provides a composition and method for determining compliance with a medication regimen. This composition and method is rapid, simple, and inexpensive. In one embodiment, it includes an orally administrable composition in combination with at least one visual marker. This marker is present in a form and amount sufficient to cause a contact staining of at least a portion of a mucous membrane or buccal membrane of the oral and/or pharyngeal cavity of a patient. In various embodiments of the invention, by way of non-invasive observation of this contact staining of the mucous or buccal membrane of the oral/pharyngeal cavity, one may obtain information regarding patient compliance with a medication regimen, such as whether the medication has been taken, the time elapsed since the medication was last taken, whether it is time for another dose of medication, etc. Thus, the present invention is very rapid, simple, and non-invasive as opposed to more invasive, tedious, and complicated monitoring methods, of the prior art such as the analysis of urine and stool samples.

Claim Rejections 35 U.S.C. § 102:

The Examiner has rejected claims 15-20 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,303,102 (the Schlichte '102 patent). In particular, regarding claim 15, the Examiner states that the Schlichte '102 patent

discloses a marker in combination with one or more treatment drugs, medicaments, or a composition applied topically or orally, wherein the marker is a pigment or dye providing visual evidence for gauging the application and time since the application of the medicine. Applicants respectfully disagree with the rejection under 35 U.S.C. § 102.

Regarding the Schlichte '102 patent, Applicants note that the entire patent is directed only to use in cutaneous or subcutaneous tissues. (See at least the title; column 2, lines 19-20; column 2, lines 33-34; and column 5, lines 16-19.) In contrast, Applicants submit that claim 15 of the present application, as presently amended, recites the marker as causing contact staining of a mucous or buccal membrane of the oral and/or pharyngeal cavity. Applicants further submit that the mucous and buccal membranes of the oral and/or pharyngeal cavity cannot be classified as cutaneous or subcutaneous tissues. The teaching in the Schlichte '102 reference teaches only some marking of such cutaneous or subcutaneous tissue primarily through injection, such as into the cutaneous or subcutaneous tissue. Alternatively, if given orally it would have to biologically work its way through the animal's system to appear in cutaneous or subcutaneous tissue. For example, the reference teaches that an innoculation would mark the underside of a hide, the hide itself (cutaneous) or the fat at the injection site. Another alternative is an implant(subcutaneous). Nowhere is there a teaching or even a hint in the Schlichte '102 reference regarding a marker which is active for contact staining a portion of a mucous membrane or buccal membrane of the oral/pharyngeal

cavity. Thus, Applicants respectfully assert that the Schlichte '102 patent does not disclose each and every limitation of claim 15 of the present application. Applicants thus respectfully request a withdrawal of the rejection of claim 15, and dependent claims 16-20, under 35 U.S.C. § 102(e).

Claim Rejections 35 U.S.C. § 103:

The Examiner has rejected claims 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over the Schlichte '102 patent in view of U.S. Patent No. 6,200,604 (the Pather '604 patent). In particular, the Examiner states that the Pather '604 patent discloses carmine and FD&C dyes, and that it would have been obvious to use such dyes in the marker composition of the Schlichte '102 patent for oral consumption, as taught by the Pather '604 patent. Applicants respectfully disagree.

With respect to the disclosure of the Schlichte '102 patent, as described above with respect to the § 102 rejection, Applicants respectfully submit that the Schlichte '102 patent only discloses a composition that is directed into cutaneous or subcutaneous tissues of a subject. The disclosure in the Schlichte '102 reference teaches only some marking of such cutaneous or subcutaneous tissue, through methods such as injection and implantation into the cutaneous or subcutaneous tissue. Nowhere is there a teaching in the Schlichte '102 reference regarding a marker which is active for contact staining a portion of a mucous membrane or buccal membrane of the oral/pharyngeal cavity. By contrast, claim 15 of the present application as presently amended, from which claims 21 and 22 ultimately depend, recites that contact staining

occurs in a mucous or buccal membrane of the oral and/or pharyngeal cavity. Applicants submit that such contact staining, as recited in the claims of the present application, is clearly very different from the marking of the cutaneous or subcutaneous tissue through the very invasive methods taught by the Schlichte '102 reference. Thus, even if one were to combine the dyes of Pather with the composition of Schlichte, Applicant submits that such a combination would not teach each and every limitation of the claims since the composition would be directed into cutaneous or subcutaneous tissues. Thus, Applicants respectfully request a withdrawal of the rejection of claims 21 and 22 under 35 U.S.C. § 103.

The Examiner has rejected claims 23-27 under 35 U.S.C. § 103(a) as being unpatentable over the Schlichte '102 patent in view of U.S. Patent No. 5,776,783 (the Kell '783 patent). In particular, the Examiner states that the Schlichte '102 patent discloses a composition having multiple medications, but does not disclose a marker associated with each medicament. The Examiner then asserts that the Kell '783 patent teaches a composition having multiple medications and separate markers associated with each medication in the formulation to monitor compliance with drug ingestion. The Examiner states that it therefore would have been obvious to provide multiple medications with markers associated with each medication in the composition of the Schlichte '102 patent wherein each marker has a unique coloring characteristic and residence time in the tissue to monitor compliance with drug ingestion, as taught by the Kell '783 patent. The Examiner finally asserts that the marker may be any color and is

visible under a variety of lighting conditions, as taught by the Schlichte '102 patent. Applicants respectfully disagree with the rejection of claims 23-27 under 35 U.S.C. § 103.

With respect to the disclosure of the Schlichte '102 patent, as described above with respect to the § 102 rejection, Applicants respectfully submit that the Schlichte '102 patent only discloses a composition that is directed into tissues of a subject. The disclosure in the Schlichte '102 reference teaches only some marking of such cutaneous or subcutaneous tissue, through methods such as injection and implantation into the cutaneous or subcutaneous tissue. Nowhere is there a teaching in the Schlichte '102 reference regarding a marker which is active for contact staining a portion of a mucous membrane or buccal membrane of the oral/pharyngeal cavity. By contrast, claim 15 of the present application as presently amended, from which claims 23-27 ultimately depend, recites that contact staining occurs in a mucous or buccal membrane of the oral and/or pharyngeal cavity. As above, Applicants submit that such contact staining, as recited in the claims of the present application, is clearly very different from the marking of the cutaneous or subcutaneous tissue through the very invasive methods taught by the Schlichte '102 reference. Thus, even if one were to combine the multiple markers of Kell with the composition of Schlichte, Applicant submits that such a combination would not teach each and every limitation of the claims, since the composition would be directed into cutaneous and subcutaneous tissues.

Further, Applicants assert that, were one to combine the Schlichte '102 patent and the Kell '783 patent, the combination does not teach the invention because the Kell '783 patent discloses a method of monitoring patient compliance with a medical regimen by testing the urine of a patient. Analysis of urine is a process that is time consuming, intrusive, requires scheduling, and requires the presence of a trained technician. These are the very drawbacks of current monitoring methods, described in the "Background of the Invention" section of the present application, that the present invention eliminates. In fact, urine analysis was one of the prior art monitoring methods that was discussed in the present application as wholly different than the compliance monitoring composition and method of the present invention. The present invention is rapid, simple, non-invasive, and inexpensive in that it is simply performed by observing a mucous or buccal membrane of the oral/pharyngeal cavity after oral ingestion for contact staining in order to determine compliance. Applicants thus respectfully assert that even if one were to attempt to detect the coloring agent of the Schlichte '102 patent, it could not be detected in the urine by the method disclosed by the Kell '783 patent, since such coloring agent would not be detectable in a patient's urine. Nor would such a coloring agent be visually observable in a patient's urine.

In view of the above, Applicants respectfully request a withdrawal of the rejection of claims 23-27 under 35 U.S.C. § 103(a).

The Examiner has rejected claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,068,981 (the Rittenburg '981 patent) in view of the

Schlichte '102 patent. In particular, the Examiner states that the Rittenburg '981 patent discloses a method of monitoring compliance of a patient in a therapeutic or medication regimen wherein the method includes the steps of providing a therapeutic compound and a marker that passes into tissue and detecting the marker in the tissue. The Examiner then further states that it would have been obvious to one of ordinary skill in the art to use a detectable compound that colors tissues in the mouth, as taught by the Schlichte '102 patent in the method of the Rittenburg '981 patent to provide visual evidence for gauging the application and time since application of the medicament. Applicants respectfully disagree.

With respect to the disclosure of the Schlichte '102 patent, as described above with respect to the § 102 rejection, Applicants respectfully submit that the Schlichte '102 patent only discloses marking of cutaneous or subcutaneous tissues in the subject. The disclosure in the Schlichte '102 reference teaches only some marking of such cutaneous or subcutaneous tissue, through methods such as injection and implantation into the cutaneous or subcutaneous tissue. Nowhere is there a teaching in the Schlichte '102 reference regarding a marker which is active for contact staining a portion of a mucous membrane or buccal membrane of the oral/pharyngeal cavity. By contrast, claim 1 of the present application as presently amended, from which claims 2-7 ultimately depend, recites that contact staining occurs in a mucous or buccal membrane of the oral and/or pharyngeal cavity. Applicants submit that such contact staining, as recited in the claims of the present application, is clearly very different from

the marking of the cutaneous or subcutaneous tissue through the very invasive methods taught by the Schlichte '102 reference. Further, the Rittenburg '981 patent does not teach contact staining of the mucous or buccal membrane of the oral and/or pharyngeal cavity. Further, Rittenburg does not disclose visualization of the oral/pharyngeal cavity. Rather, Applicants submit that Rittenburg discloses a compound that passes into a system (such as bloodstream, excretory, or other fluid or tissue), and then detects a marker in a fluid or tissue sample taken from the subject. Thus, even if one were to combine the method of Rittenburg with the composition of Schlichte, such a combination would not teach each and every limitation of the claims.

Applicants thus respectfully request a withdrawal of the rejection of claims 1-7 under 35 U.S.C. § 103(a) over the Rittenburg '981 patent in view of the Schlichte '102 patent.

The Examiner has rejected claims 8 and 9 under 35 U.S.C. § 103(a) as being unpatentable over the Rittenburg '981 patent in view of the Schlichte '102 patent, and further in view of the Pather '604 patent. In particular, the Examiner states that it would have been obvious to one of ordinary skill in the art to use carmine dyes or FD&C dyes, as disclosed in the Pather '604 patent, in the method of the combination of the Rittenburg '981 and Schlichte '102 patents. Applicants respectfully disagree.

In particular, as described above with respect to the rejection of claims 1-7, the combination of the Schlichte '102 patent and Rittenburg '981 patent do not disclose all the limitations of claim 1 of the present invention, from which claims 8 and 9

ultimately depend. In particular, the Schlichte '102 patent discloses use of its compositions only in cutaneous or subcutaneous tissues, not contact stainnig or observation in mucous or buccal membranes. Nor does the Rittenburg '981 patent disclose observation in the mucous or buccal membranes. Thus, any combination of the Schlichte '102 patent disclosure with the method described in the Rittenburg patent would not disclose each and every limitation of the present application, since the combination of those two patents would not disclose contact staining in a mucous or buccal membrane of the oral and/or pharyngeal cavity of the patient. Thus, since claim 1 would not be rendered obvious, Applicants respectfully submit that neither would claims 8 and 9 be rendered obvious in further view of the Pather '604 patent. Applicants thus respectfully request a withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. § 103(a).

The Examiner has rejected claims 10-14 under 35 U.S.C. § 103(a) as being unpatentable over the Rittenburg '981 patent in view of the Kell '783 patent further in view of the Schlichte '102 patent. In particular, the Examiner states that it would have been obvious to provide a composition with multiple medicaments in the combination of Rittenburg and Kell, wherein each maker has unique coloring characteristics, residence time, and lighting conditions, as taught by Schlichte. Applicants respectfully disagree.

With respect to the disclosure of the Schlichte '102 patent, as described above with respect to the § 102 rejection, Applicants respectfully submit that the

Schlichte '102 patent only discloses use of the composition as directed into cutaneous or subcutaneous tissues. Thus, it does not disclose contact staining in the mucous or buccal membranes. Neither do Rittenburg or Kell disclose contact staining of the mucous or buccal membranes. Further, the method of Rittenburg discloses detecting marker in a body fluid or tissue that has been collected, while Kell discloses detecting a marker in a urine sample. By contrast, claim 1 of the present application, from which claims 10-14 ultimately depend, recites that contact staining occurs and is visualized in a mucous or buccal membrane of the oral and/or pharyngeal cavity. Thus, Applicant submits that even if one were to combine the disclosures of Rittenburg, Kell, and Schlichte, such a combination would not teach each and every limitation of the claims.

Further, Applicants assert that even were one to combine the Schlichte '102 patent and the Kell '783 and Rittenburg '981 patents, the combination does not teach the invention. In particular, as described above, the Schlichte '102 patent discloses a composition which may mark only a cutaneous or subcutaneous tissue. The Kell '783 patent discloses a method of monitoring patient compliance with a medical regimen by testing the urine of a patient. Applicants thus respectfully assert that even if one were to attempt to detect the coloring agent of the Schlichte '102 patent, it could not be detected in the urine by the method disclosed by the Kell '783 patent, since such coloring agent would not be detectable in a patient's urine. Nor would such a coloring agent be visually observable in a patient's urine. Applicants further assert that the combination of Rittenburg with Schlichte would fail for the same

reasons as the combinations of Kell and Schlichte.

Thus, Applicants respectfully request a withdrawal of the rejection of claims 10-14 under 35 U.S.C. § 103(a).

Conclusion:

For the foregoing reasons, Applicant submits that all claims are patentable and a Notice of Allowance is respectfully requested.

No fee is believed due with this submission. However, if any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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